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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------|
| 09/936,190  | 12/09/2001  | Richard A. Dixon     | NBLE:026US                  | 2623             |
| 7590  | 03/24/2004  |                      |                             |                  |
| Robert E. Hanson<br>FULBRIGHT & JAWAORSKI LLP<br>600 Congress Avenue Suite 2400<br>Austin, TX 78701 |             |                      | EXAMINER<br>KALLIS, RUSSELL |                  |
|   |             |                      | ART UNIT                    | PAPER NUMBER     |
|   |             |                      | 1638                        |                  |

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,190

Applicant(s)

DIXON ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, 9-11, 13-14, 17, 19-24, 27-29, 32 and 34-36 drawn to a method for introducing a DNA segment encoding a flavanone to isoflavanone converting enzyme into a non-isoflavonoid producing species of plant that also expresses chalcone synthase, chalcone reductase, and chalcone isomerase; and further comprises downstream genes to metabolize isoflavanone or isoflavone to isoflavanoid derivatives, wherein the DNA segment is SEQ ID NO: 1 from soybean.

Group II, claim(s) 1-6, 9-14, 18-24, 27-30, 33, 35-36 and 38-41 drawn to a method for introducing a DNA segment encoding a flavanone to isoflavanone converting enzyme into a non-isoflavonoid producing species of plant that also expresses chalcone synthase, chalcone reductase, and chalcone isomerase; and further comprises downstream genes to metabolize isoflavanone or isoflavone to isoflavanoid derivatives, wherein the DNA segment is SEQ ID NO: 4 from *Medicago truncatula*.

Group III, claim(s) 37 and 42, drawn to a protein that converts a flavanone to isoflavanone.

Group IV, claim(s) 7-11, 13, 14, 25-29, 32 and 34-36 drawn to a method for increasing the level of isoflavonoid compounds in naturally isoflavonoid producing plants by introducing a DNA segment encoding a flavanone to isoflavanone converting enzyme and is also transformed to further comprise chalcone synthase, chalcone reductase, and chalcone isomerase, wherein the DNA segment is SEQ ID NO: 1 from soybean.

Group V, claim(s) 7-14, 25-30, 33, 35-36 and 38-41 drawn to a method for increasing the level of isoflavonoid compounds in naturally isoflavonoid producing plants by introducing a DNA segment encoding a flavanone to isoflavanone converting enzyme and is also transformed to further comprise chalcone synthase, chalcone reductase, and chalcone isomerase, wherein the DNA segment is SEQ ID NO: 4 from *Medicago truncatula*.

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Group VI, claim(s) 15 and 17, drawn to a method of synthesizing an isoflavanone intermediate or an isoflavone from a flavanone by expressing a recombinant CYP93C gene segment in a suitable bacterial, fungal, algal, or insect host wherein the DNA sequence is SEQ ID NO: 1 from soybean.

Group VII, claim(s) 15 and 18, a method of synthesizing an isoflavanone intermediate or an isoflavone from a flavanone by expressing a recombinant CYP93C gene segment in a suitable bacterial, fungal, algal, or insect host wherein the DNA sequence is SEQ ID NO: 4 from *Medicago truncatula*.

Group VIII, claim(s) 44-50 drawn to a method of using a transgenic plant that exhibits increased levels of an isoflavonoid when transformed with a DNA segment encoding a flavanone to isoflavanone converting enzyme by isolating the isoflavanoids and adding to a food and to a method of using a transgenic plant that exhibits increased levels of isoflavonoids as a food by ingesting said plant or portion of said plant.

Group IX, claim(s) 51, drawn to a method of making a pharmaceutical preparation by isolating and formulating the isoflavonoid from a plant having an introduced DNA segment encoding a flavanone to isoflavanone converting enzyme.

Group X, claim(s) 43, 52-65, drawn to a method of transforming a plant with a DNA segment encoding a cytochrome P450 that catalyzes aryl migration of a flavanone to an isoflavanone.

The inventions are not linked because the special technical feature of Group I of introducing into a plant a DNA segment encoding an enzyme that catalyzes the aryl migration of a flavanone to form an isoflavanone intermediate or isoflavone i.e. a CYP93C1 cDNA from soybean, was known in the art. Siminszky B. *et al.*, PNAS, February 1999, Vol. 96, pages 1750-1755; teach the expression of a soybean P450 monooxygenase cDNA (CYP93C1) in yeast and in tobacco and the enhancement of metabolism of phenylurea herbicides. Further, the soybean CYP93C1 polynucleotide was made publicly available on January 2, 1998.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A handwritten signature in black ink, appearing to read 'Ashwin D. Mehta', is written over a faint, larger signature.

**ASHWIN D. MEHTA, PH.D**  
**PATENT EXAMINER**

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.  
March 22, 2004